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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,377	10/24/2003	James Hunter Boone	TLAB.100292	1630

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,377	BOONE ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-10,12,17,20 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-10,12,17,20 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2.5/2004;7/2006;9/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amended Claims 1-2, 8-10, 12, 17, 20, and new claims 30-32 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 21, 2009 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed September 21, 2009 has been considered.

Objections/Rejections Withdrawn

1. ***Withdrawn Claim Objections*** Claims 6-7 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, has been obviated by claim cancellation.

2. Withdrawn ***Double Patenting,*** The rejection of claim 24, 27 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 2004/0033537 (10/629,975) is herein withdrawn in light of the cancellation of these claims.

3. Withdrawn Double Patenting, The rejection of claim 24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,192,724) is herein withdrawn in light of the cancellation of the claim.

4. ***Withdrawn, Claim Rejections - 35 USC § 102*** The rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Guerrant et al (US Pat. 5,124,252) is herein withdrawn in light of the cancellation of the claim.

5. ***Withdrawn,*** The rejection of claims 24 and 27 under 35 U.S.C. 102(b) as being anticipated by Fine et al (AJG, 1998) is herein withdrawn in light of the cancellation of these claims.

6. ***Withdrawn, Claim Rejections - 35 USC § 103*** The rejection of claims 1-3,6-10, 24 and 27 under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al (2000) in view of Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001) is herein withdrawn in light of the amendment of claims to recite a combination of claim limitations not taught or suggested in the applied prior art, or the cancellation of claims.

Response to Arguments

3. In so far as the prior art of record does not teach the claim limitations recited in original claim 11, these claim limitations having been incorporated into independent claim 1, these art rejections have been obviated.

Rejections Maintained/Response to Arguments

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. The rejection of claims 1-2, 8-12, 17,20 and new claims 30-32 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7-14 of copending Application No. PG-pub 2004,0126898 (10/656,034)) is responded to by Applicant by stating that a Terminal Disclaimer was filed September 21, 2009 with the Amendment/Remarks submitted in response to the Office Action dated May 21, 2009.

9. Upon consideration of the instant Applications file history, a Terminal Disclaimer was Not found; therefore the obviousness type double patenting rejection is maintained for reasons of record.

10. The examiner is maintaining the rejection for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending species anticipates the instantly claimed genus of methods, wherein the instant claims do not require the measurement of specific type of immunoglobulin antibodies as claimed in copending claim 13 that measures IgG, IgE, IgM, IgD, IgAsec, IgA and lactoferrin is disclosed to be elevated in subject with disease activity: **[0018] There were 51 ulcerative colitis (UC) patients, 47 Crohn's** disease (CD) patients, 7 irritable bowel patients (IBS), and 11 healthy (H) adults recruited for the study. Fecal specimens were collected from each enrolled patient and stored at -

70.degree. C. until tested. Specimen consistency ranged from solid to liquid. The level of fecal ANCA was determined using the qualitative ANCA ELISA as previously described. Disease activity was defined using **elevated fecal lactoferrin** as an indicator of intestinal inflammation. A **dilution** of 1:10 was used in the qualitative ELISA test and results were reported as positive (absorbance values >0.140) or negative (absorbance values <0.140). The mean optical densities, standard deviation and P values (two-tailed student T-test 'with unequal variance) were determined for the ANCA positive ulcerative colitis patients. Of the 26 patients that tested positive for fecal ANCA, there were four patients had Crohn's Disease, 21 had ulcerative colitis and one patient was healthy. ANCA-positive ulcerative colitis showed a mean.+-.SD OD.sub.450 of 0.311.+-.0.166. The mean optical density for the ulcerative colitis patients was significantly different from IBS and healthy persons (p value<0.0005). A summary of the statistical analysis is listed in Table 2.This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection

4. Applicant's arguments filed September 21, 2008 have been fully considered with respect to claims have been considered but are moot in view of the new ground(s) of rejection under Obviousness Type Double Patenting. Upon further consideration of the obviousness type double patenting rejection over PG-Pub 2004/0126898(above) and issued Patents 7,192, 724 and 7,560,240, in light of Nielson, Targan and Fine, Applicant's claims stand rejected as set forth below or for reasons of record.

5. Claims 1-2,8-10,12,17,20, and new claims 30-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,192,724 (three common inventors) in view of Nielson et al(2000, reference of record), Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001).

US Patent 7,192,724 (three common inventors) in view of Nielson et al obviate the instantly claimed invention because the allowed claims are directed to a genus of methods of detecting fecal lactoferrin in a diluted fecal sample to determine the presence or absence of inflammatory bowel disease (IBD) and teaches the importance of distinguishing between types of IBD (see Tables XI, XII and XIII) as compared to inflammatory bowel syndrome(IBS), and

the instantly claimed invention also measures fecal lactoferrin in a diluted sample to determine the presence or absence of inflammatory bowel disease and additionally carries out methods steps to distinguish between UC and CD inflammatory bowel diseases (IBD).

The allowed genus of methods of detecting IBD encompasses the instantly claimed methods in light of Nielsen et al who teach Lactoferrin to be a fecal marker for inflammatory bowel disease (see page 360, col. 2, lines 3-5) and the importance of measuring ASCA and ANCA for distinguishing UC from Crohn's disease, wherein pANCA is more common in UC than CD (see page 361, col. 2, paragraph 1) and that ASCA, antibodies are more common to Crohn's disease (see page 361, col. 2, paragraph 2). It would have been obvious to include the measurement of UC and CD specific markers in the method of '724 because both methods measure the presence of lactoferrin in a diluted fecal sample and Nielson teach UC and CD are both inflammatory bowel diseases that can be distinguished based upon measuring ASCA and ANCA antibodies in a biological sample and Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001) teach ASCA and ANCA can be measured in fecal samples. The instantly claimed species of methods that carries out additional methods steps is an obvious species encompassed by the allowed genus.

6. Claims 1-2,8-10,12,17,20, and new claims 30-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,560,240 (three common inventors, filing date 2003) in view of Nielson et al(2000, reference of record), Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001).

US Patent 7,560,240 (three common inventors) in view of Nielson et al, Targan et al (1995) and Fine, obviate the instantly claimed invention because the allowed claims are directed to a genus of methods of detecting fecal lactoferrin in a diluted fecal sample to determine the presence or absence of inflammatory bowel disease (IBD) and teaches the importance of distinguishing between types of IBD (see Tables XI, XII, XIII and XIV, col. 13-14) as compared to inflammatory bowel syndrome(IBS), and the instantly claimed invention also measures fecal lactoferrin in a diluted sample to determine the presence or absence of inflammatory bowel disease and additionally carries out methods steps to distinguish between UC and CD inflammatory bowel diseases (IBD).

The allowed genus of methods of detecting IBD encompasses the instantly claimed methods in light of Nielsen et al who teach Lactoferrin to be a fecal marker for inflammatory bowel disease (see Nielsen, page 360, col. 2, lines 3-5) and the importance of measuring ASCA and ANCA for distinguishing UC from Crohn's disease, wherein pANCA is more common in UC than CD (see Nielsen, page 361, col. 2, paragraph 1) and that ASCA antibodies are more common to Crohn's disease (see Nielsen, page 361, col. 2, paragraph 2).

It would have been obvious to include the measurement of UC and CD specific markers in the method of '240 because both methods measure the presence of lactoferrin in a diluted fecal sample and Nielson teach UC and CD are both inflammatory bowel diseases that can be distinguished based upon measuring ASCA and ANCA antibodies in a biological sample and Targan et al (1995) and Fine (PG-Pub 2001/0036639A1, filing date March 2, 2001) teach ASCA and ANCA can be measured in fecal samples. The instantly claimed species of methods that carries out additional methods steps to diagnose inflammatory bowel disease in a diluted fecal

sample based upon the presence of elevated fecal lactoferrin levels is an obvious species encompassed by the allowed genus in view of Nielson, Targan and Fine.

Conclusion

11. This is a non-final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

/Ginny Portner/
Examiner, Art Unit 1645
December 14, 2009